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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,615	09/15/2003	Edward H. Overstreet	AB-367U	9758

23845 7590 04/05/2005

ADVANCED BIONICS CORPORATION
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VALENCIA, CA 91355

EXAMINER

GREENE, DANA D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,615

Applicant(s)

OVERSTREET, EDWARD H.

Examiner

Dana D. Greene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7-19-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-13 stand rejected under 35 U.S.C. §102(b) as being anticipated by Faltys (US 6,157,861, hereinafter "Faltys"). Faltys is considered to disclose:

a method for fitting a cochlear implant system to a patient, the cochlear implant system having a multiplicity of electrode contacts and means for delivering electrical stimuli to a selected electrode contact or a selected group of electrode contacts (see col. 4, ln. 60-65, Faltys). The disclosed method of determining a suitable range of stimulus intensity for an implantable cochlear stimulator (ICS) is considered to anticipate the claimed method of fitting a cochlear implant system to a patient because both refer to the process of determining and setting the amplitude or intensity of stimuli generated by the ICS to a level or setting that is effective for the patient.

With reference to claims 8-10, Faltys teaches a step applying an amplitude modulated pulse train at a known intensity level and having a rate that mimics live speech (see col. 1, ln. 50-65, Faltys).

Referring to claims 11-13, Faltys teaches a method of visually observing the stapedial reflex and measuring change in the impedance of the tympanic membrane

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(see col. 4, ln. 20-25, Faltys). The disclosed self-adjusting ICS measure change by using specialized electrodes near the tympani muscle or stapedius.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 14-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Maltan (US 6,415,185, hereinafter Maltan) in view of Faltys. Maltan is considered to disclose:

a cochlear implant system comprising a multiplicity of electrode contacts; means for applying electrical stimuli of a known intensity level to each of the defined groups of electrode contacts (see col. 2, ln. 45-55, Maltan). Maltan discloses a cochlear implant device with permanently implanted electrodes connected to the cochlear device (see col. 2, ln. 25-26, Maltan). The disclosed electrode contacts are considered to anticipate

the claimed contacts because both are capable of receiving an electrical stimulus of known intensity.

Maltan is considered to disclose the claimed invention as discussed above except for the means for observing a stapedial reflex criteria of a patient within whom the cochlear implant system is adapted to be implanted; means for adjusting the intensity of the electrical stimuli applied to each group of electrode contacts until a stapedial reflex criteria of the patient is observed. However, Faltys is considered to teach the claimed means for observing the stapedial reflex criteria (see col. 6, ln. 64-67, Faltys). It would have been obvious to one of ordinary skill in the art to combine the teachings of Maltan with the considered impedance bridge configuration teaching found in Faltys for the purpose of observing and adjusting the stapedial reflex.

Also, Maltan fails to teach the claimed means for remembering the intensity level of the electrical stimuli that produced the stapedial reflex for each group of electrode contacts. However, Faltys is considered to teach this remembering means (see col. 3, ln. 45-55, Faltys). It would have been obvious to one of ordinary skill in the art to combine the teachings of Maltan with the EMG of Faltys for the purpose of using the remembered intensities for each group of electrode contacts as parameter settings for controlling the intensity of electrical stimuli thereafter applied through the electrode contacts by the implant system.

Claims 2-4 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Maltan in view of Faltys. Maltan is considered to disclose the claimed invention as discussed above except for the claimed method of modulating the amplitude of the

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pulse trains of the electrical stimuli. However, Faltys is considered to disclose this method as exemplified in the adjustment of the base amplitude or intensity of the various stimuli generated by the ICS from the factory settings to values comfortable for the patient (see col. 1, ln. 50-55, Faltys). It would have been obvious to one of ordinary skill in the art to combine the teachings of Maltan with the adjustment of amplitudes as taught in Faltys for the purpose of obtaining the advantages of using modulated electrical stimuli.

With reference to claims 15-19, Faltys is considered to disclose the criteria for observing stapedial reflex as they relate to the cochlear implant system (see col. 4, ln. 20-25, Faltys). It would have been obvious to one of ordinary skill in the art to combine the teachings of Maltan with the criteria of Faltys for the purpose of visually observing the stapedial reflex and measuring change in the impedance of the tympanic membrane.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-0276.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene



George Manuel
Primary Examiner